Revofer™ Injection

Ferric Carboxymaltose INN

Composition

Revofer™ 500 IV Injection: Each 10 ml contains Ferric Carboxymaltose INN equivalent to elemental Iron 500 mg.
Revofer™ 750 IV Injection: Each 15 ml contains Ferric Carboxymaltose INN equivalent to elemental Iron 750 mg.
Revofer™ 1gm IV Injection: Each 20 ml contains Ferric Carboxymaltose INN equivalent to elemental Iron 1,000 mg.

Pharmacology

Ferric Carboxymaltose is a colloidal Iron (III) Hydroxide in complex with Carboxymaltose, a carbohydrate polymer that releases Iron.

Indication

Revofer™ is indicated for the treatment of:

- Iron deficiency anemia (IDA) in:
  adult and pediatric patients 1 year of age and older who have either intolerance or an unsatisfactory response to oral iron.
  adult patients who have non-dialysis dependent chronic kidney disease.
- Iron deficiency in adult patients with heart failure and New York Heart Association class II/III to improve exercise capacity.

Dosage and Administration

Recommended Dosage for Treatment of Iron Deficiency Anemia

- For patients weighing 50 kg (110 lb) or more: **Revofer**™ should be given in two doses separated by at least 7 days. Each dose should be given as 750 mg for a total cumulative dose of 1,500 mg of iron per course. An alternative dose of **Revofer**™ 15 mg/kg to a maximum of 1,000 mg may be administered as a single-dose treatment course.
- For patients weighing less than 50 kg (110 lb): **Revofer**™ should be given intravenously as 15 mg/kg body weight in two doses separated by at least 7 days per course.

Recommended Dosage in Patients with Iron Deficiency with Heart Failure

	Weight less than 70 kg			Weight 70 kg or more		
	Hb (g/dL)			Hb (g/dL)		
	< 10	10 to 14	> 14 <15	< 10	10 to 14	> 14 to <15
Day 1	1,000 mg	1,000 mg	500 mg	1,000 mg	1,000 mg	500 mg
Week 6	500 mg	-	-	1,000 mg	500 mg	-

Method of Administration

Revofer™ must be administered only by the intravenous route: by bolus injection or by infusion. It must be diluted only in sterile 0.9% Sodium Chloride solution as shown in the below table:

Volume of Revofer™	Equivalent Iron Dose (mg)	Maximum amount of Sterile 0.9% Sodium Chloride solution	Minimum Administration Time
10 ml	500 mg	100 ml	6 minutes
15 ml	750 mg	250 ml	15 minutes
20 ml	1,000 mg	250 ml	15 minutes

Contraindication

Hypersensitivity to the active substance or any of its excipients.

Warning & Precaution

- Parenterally administered iron preparations can cause hypersensitivity reactions including serious and potentially fatal anaphylactic reactions.
- Transient elevations in systolic blood pressure, sometimes occurring with facial flushing, dizziness, or nausea were observed. These elevations generally occurred immediately after dosing and resolved within 30 minutes.
- Symptomatic hypophosphatemia has been reported after one dose & in most cases, it is resolved within three months. Correct pre-existing hypophosphatemia prior to initiating therapy.
- In the 24 hours following administration of Ferric Carboxymaltose, laboratory assays may overestimate serum iron and transferrin bound iron by also measuring the iron in Ferric Carboxymaltose.

Side Effect

The most common side effects of Ferric Carboxymaltose include nausea, high blood pressure, flushing, low levels of phosphorous in blood, dizziness, vomiting, headache and pain or bruising at the injection site.

Drug Interaction

The absorption of oral iron is reduced when administered concomitantly with parenteral iron preparations. Therefore, if required, oral iron therapy should not be started for at least 5 days after the last administration of Ferric Carboxymaltose.

Use in Pregnancy and Lactation

Pregnancy: There are limited data from the use of Ferric Carboxymaltose in pregnant women. A careful benefit/risk evaluation is required before use during pregnancy and Ferric Carboxymaltose should not be used during pregnancy unless clearly necessary.
Lactation: Ferric Carboxymaltose is excreted in human milk which is unlikely to affect the baby.

Pediatric Use

Ferric Carboxymaltose is not recommended in children less than 1 year.

Overdose

Administration of Ferric Carboxymaltose in quantities exceeding the amount needed to correct iron deficit at the time of administration may lead to accumulation of iron in storage sites eventually leading to haemosiderosis.

Storage Condition

Store below 30° C, away from light. Keep all medicines out of the reach of children.

How Supplied

Revofer™ 500 IV Injection: Each box contains one vial of 10 ml Ferric Carboxymaltose solution with one bottle of 100 ml 0.9% Sodium Chloride solution, one infusion set, one alcohol pad, one first aid band & one 10 ml sterile disposable syringe.
Revofer™ 750 IV Injection: Each box contains one vial of 15 ml Ferric Carboxymaltose solution with one bottle of 250 ml 0.9% Sodium Chloride solution, one infusion set, one alcohol pad, one first aid band & one 20 ml sterile disposable syringe.
Revofer™ 1gm IV Injection: Each box contains one vial of 20 ml Ferric Carboxymaltose solution with one bottle of 250 ml 0.9% Sodium Chloride solution, one infusion set, one alcohol pad, one first aid band & one 20 ml sterile disposable syringe.

Manufactured by
SQUARE
PHARMACEUTICALS PLC.
Bangladesh